

Liza M. Walsh, Esq.
Agnes Antonian, Esq.
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Tel.: (973) 535-0500
Fax: (973) 535-9217
Attorneys for Plaintiffs
Hospira, Inc. and Orion Corporation

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HOSPIRA, INC. and ORION CORPORATION,

Plaintiffs,

v.

SANDOZ INTERNATIONAL GmbH and
SANDOZ, INC.

Defendants.

CIVIL ACTION No. 3:09-cv-04591 (MLC/TJB)

**HOSPIRA, INC. AND
ORION CORPORATION'S
ANSWER TO COUNTERCLAIMS**

Plaintiffs and Counterclaim Defendants Hospira, Inc. ("Hospira") and Orion Corporation ("Orion"), by their undersigned counsel, hereby answer the Counterclaims of Defendant and Counterclaim Plaintiff Sandoz Inc. ("Sandoz") as follows:

JURISDICTION AND VENUE

1. Plaintiffs admit that Sandoz purports to base subject matter jurisdiction on 28 U.S.C. §§ 1331, 1338(a), and 1367(a).

2. Plaintiffs do not contest venue in this district regarding these counterclaims.

FIRST COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the '214 Patent)

3. No response is required to the general incorporation of the allegations set forth in paragraphs 1-47 of Sandoz's Answer and paragraphs 1-9 of its Affirmative Defenses. Plaintiffs hereby incorporate by reference their responses to paragraphs 1 and 2 of Sandoz's Counterclaims.

4. Denied.

5. Plaintiffs admit that an actual controversy exists as to whether Sandoz infringes the '214 patent, and otherwise deny the remaining allegations of paragraph 5.

SECOND COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '214 Patent)

6. No response is required to the general incorporation of the allegations set forth in paragraphs 1-47 of Sandoz's Answer and paragraphs 1-9 of its Affirmative Defenses. Plaintiffs hereby incorporate by reference their responses to paragraphs 1 through 5 of Sandoz's Counterclaims.

7. Denied.

8. Plaintiffs admit that an actual controversy exists regarding the validity of the '214 patent, and otherwise deny the remaining allegations of paragraph 8.

THIRD COUNTERCLAIM

(Declaratory Judgment of Unenforceability of the '214 Patent)

9. No response is required to the general incorporation of the allegations set forth in paragraphs 1-47 of Sandoz's Answer and paragraphs 1-9 of its Affirmative Defenses. Plaintiffs hereby incorporate by reference their responses to paragraphs 1 through 8 of Sandoz's Counterclaims.

10. Denied.

11. Denied.

12. Plaintiffs admit that the claims of the '214 patent cover dexmedetomidine and its pharmaceutically acceptable salts and pharmaceutical compositions containing dexmedetomidine and its pharmaceutically acceptable salts, as well as methods of using dexmedetomidine and its pharmaceutically acceptable salts. Plaintiffs admit that dexmedetomidine is the d-isomer of medetomidine, that racemic medetomidine contains equal amounts of d- and l-medetomidine and that dexmedetomidine is an α_2 -adrenergic receptor agonist. Plaintiffs also admit that the '214 patent states, at col. 2, lines 23-27, "[i]n animal experiments, the d- and l- enantiomers of the present invention and especially the d-enantiomer, have proved to possess highly enhanced α_2 -selectivity and potency compared to the racemic mixture (i.e. medetomidine)." Plaintiffs otherwise deny the allegations of paragraph 12.

13. Plaintiffs admit that the originally filed claims of application Serial Number 07/219,637 covered, *inter alia*, the separated d- and l- enantiomers of medetomidine and their non-toxic pharmaceutically acceptable acid addition salts, methods of separating the d- and l- enantiomers of medetomidine, pharmaceutical compositions comprising a d- or l- enantiomer

of medetomidine or a non-toxic pharmaceutically acceptable acid addition salt thereof, as well as methods of using the d- and l- enantiomers of medetomidine and their non-toxic pharmaceutically acceptable salts. Plaintiffs otherwise deny the allegations of paragraph 13.

14. Plaintiffs admit that the Examiner rejected application claims 1, 2, and 5 to 8 in an Office Action dated March 17, 1989. The bases for the Examiner's rejection of those claims are stated in the Office Action. Plaintiffs otherwise deny the allegations of paragraph 14.

15. Plaintiffs admit that then-pending application claims 1, 3, 4, and 6 were cancelled in an Amendment and accompanying Remarks dated September 18, 1989. Plaintiffs admit that the Remarks presented the information found at page 3 of the Remarks, which stated that the "d-enantiomer surprisingly has a selectivity ratio [sic, ratio] of 45849, i.e., more than nine times that of the racemate." Plaintiffs admit that a Notice of Allowance was issued on October 6, 1989. Plaintiffs otherwise deny the allegations of paragraph 15.

16. Plaintiffs admit that the September 18, 1989 Amendment referenced the data in Table 2 of the '214 patent and that the α_2/α_1 selectivity ratios given for medetomidine, l-medetomidine, and d-medetomidine were stated to be 5060, 4129, and 45849 respectively. Plaintiffs admit that data in Table 2 of the '214 patent was generated at the direction of Raimo Virtanen and that Raimo Virtanen is a co-author of "Evaluation of the α_1 - and α_2 - Adrenoceptor Effects of Detomidine, a Novel Veterinary Sedative Analgesic," Eur. J. Pharmac. 108, 163-169 (1985). Plaintiffs otherwise deny the allegations of paragraph 16.

17. Denied.

18. Plaintiffs admit that the IC_{50} values for the displacement of 3H -Prazosin by medetomidine, l-medetomidine, and d-medetomidine in Table 2 of the '214 patent are 16700, 189975, and 55019, respectively, and that the September 18, 1989 Remarks referenced the 3H -Prazosin displacement data from Table 2. Plaintiffs otherwise deny the allegations of paragraph 18.

19. Plaintiffs admit that Raimo Virtanen is a co-author of "Characterization of the Selectivity, Specificity and Potency of Medetomidine as an α_2 -Adrenoceptor Agonist," Eur. J. Pharmac. 150, 9-14 (1988). Plaintiffs admit that the face of the paper indicates that the paper was received for publication on November 23, 1987, submitted as revised on February 11, 1988, and accepted on March 1, 1988, and that Table 1 of that paper reports an α_2/α_1 selectivity ratio for medetomidine, calculated as a ratio of K_i values, of 1620. Plaintiffs admit that Table 2 of the '214 patent reports an α_2/α_1 selectivity ratio for medetomidine of 5060. Plaintiffs otherwise deny the allegations of paragraph 19.

20. Denied.

21. Plaintiffs admit that Raimo Virtanen is a co-inventor of the '214 patent and that he signed a declaration acknowledging a duty to disclose information which is material to the examination of the application for the '214 patent. Plaintiffs otherwise deny the allegations of paragraph 21.

22. Denied.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

27. Paragraph 27 does not contain any factual allegations, thus no response is required.

28. Plaintiffs admit that an actual controversy exists with respect to the enforceability of the '214 patent, and otherwise deny the allegations of paragraph 28.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the '867 Patent)

29. No response is required to the general incorporation of the allegations set forth in paragraphs 1-47 of Sandoz's Answer and paragraphs 1-9 of its Affirmative Defenses. Plaintiffs hereby incorporate by reference their responses to paragraphs 1 through 28 of Sandoz's Counterclaims.

30. Denied.

31. Plaintiffs admit that an actual controversy exists as to whether Sandoz infringes the '867 patent, and otherwise deny the allegations of paragraph 31.

FIFTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '867 Patent)

32. No response is required to the general incorporation of the allegations set forth in Paragraphs 1-47 of Sandoz's Answer and paragraphs 1-9 of its Affirmative Defenses.

Plaintiffs hereby incorporate by reference their responses to paragraphs 1 through 31 of Sandoz's Counterclaims.

33. Denied.

34. Plaintiffs admit that an actual controversy exists regarding the validity of the '867 patent, and otherwise deny the remaining allegations of paragraph 34.

SIXTH COUNTERCLAIM

(Declaratory Judgment of Unenforceability of the '867 Patent)

35. No response is required to the general incorporation of the allegations set forth in Paragraphs 1-47 of Sandoz's Answer and Paragraphs 1-9 of its Affirmative Defenses. Plaintiffs hereby incorporate by reference their responses to Paragraphs 1 through 34 of Sandoz's Counterclaims.

36. Denied.

37. Denied.

38. Plaintiffs admit that that dexmedetomidine is the d-enantiomer of medetomidine and that the claims of the '867 patent cover, *inter alia*, certain methods of sedating a patient in an intensive care unit comprising administering dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the patient remains arousable and orientated. Plaintiffs otherwise deny the allegations of paragraph 38.

39. Plaintiffs admit that Riku Aantaa is a co-inventor of the '867 patent, and that Dr. Aantaa co-authored "Alpha₂-adrenergic Agents and Anaesthesia," Acta Anaesthesiol.

Scand. 37: 433-448 (1993). Plaintiffs admit that this article reviews certain literature. Plaintiffs admit that page 437 of this article contains the following passage: “The pharmacological actions of dexmedetomidine (e.g., reductions in heart rate and blood pressure after low doses, with increases in blood pressure after high doses; contraction of smooth muscle; sedation; and sleep, analgesia, and anaesthetic potentiation at high doses) closely resemble those of clonidine, but dexmedetomidine has been reported to be a complete anaesthetic by itself in sufficiently high doses in experimental animals. This may be due to dexmedetomidine’s higher intrinsic activity compared to clonidine, dexmedetomidine being a full agonist in several pharmacological models where clonidine only displays partial agonist activity.” Plaintiffs admit that page 442 of the article contains the following passage: “The greater relative potency as well as the higher selectivity and specificity of dexmedetomidine compared to clonidine have raised great expectations with regard to the anaesthetic usefulness of this drug (161). In man, the effects of medetomidine and dexmedetomidine closely resemble those induced by clonidine (162-166).” Plaintiffs otherwise deny the allegations of paragraph 39.

40. Plaintiffs admit that “Alpha₂-adrenergic Agents and Anaesthesia,” *Acta Anaesthesiol. Scand.* 37: 433-448 (1993) was not submitted to the USPTO during the prosecution of the ’867 patent. Plaintiffs otherwise deny the allegations of paragraph 40.

41. Plaintiffs admit that the ’867 patent states at col. 4, lines 30-33 that “[a]pplicants have surprisingly discovered that dexmedetomidine or a pharmaceutically acceptable salt thereof is an ideal agent to be administered to a patient in the ICU for achieving sedation and patient comfort,” and states, at col. 4, lines 49-53 “[t]he quality of sedation in the ICU achieved by administering dexmedetomidine is unique. Patients sedated by dexmedetomidine or a pharmaceutically acceptable salt thereof are arousable and oriented, which

makes the treatment of the patient easier.” Plaintiffs otherwise deny the allegations of paragraph 41.

42. Plaintiffs admit that the Remarks accompanying the Amendment dated August 9, 2002, contained the following passage at page 9: “Dexmedetomidine produces an unexpected quality of sedation not achieved by other ICU-sedatives. The compound allows for quicker titration of the level of sedation in a dose-dependent manner. Patients are asleep but easily arousable and well-oriented, calm and cooperative. They can be awakened and they can respond to questions.” Plaintiffs admit that then-pending claim 13 was amended to include the limitation “wherein the patient remains arousable and orientated” in an Amendment dated May 2, 2003, and that a Notice of Allowance issued on November 10, 2003. Plaintiffs otherwise deny the allegations of paragraph 42.

43. Plaintiffs admit that Riku Aantaa signed a declaration acknowledging the duty to disclose information which is material to the examination of the application for the ’867 patent. Plaintiffs otherwise deny the allegations of paragraph 43.

44. Plaintiffs admit that Riku Aantaa signed a declaration acknowledging the duty to disclose information which is material to the examination of the application for the ’867 patent. Plaintiffs admit that “Alpha₂-adrenergic Agents and Anaesthesia,” Acta Anaesthesiol. Scand. 37: 433-448 (1993) was not submitted to the USPTO during the prosecution of the ’867 patent. Plaintiffs otherwise deny the allegations of paragraph 44.

45. Denied.

46. Denied.

47. Denied.

48. Plaintiffs admit that each claim of the '867 patent includes the limitation that the "patient remains arousable and orientated." Plaintiffs otherwise deny the allegations of paragraph 48.

49. Denied.

50. Paragraph 50 does not contain any factual allegations, thus no response is required.

51. Plaintiffs admit that an actual controversy exists with respect to the enforceability of the '867 patent, and otherwise deny the allegations of paragraph 51.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Counterclaim Defendants pray for judgment as follows:

- A. An order dismissing each of Sandoz's Counterclaims with prejudice.
- B. An order declaring the '214 patent valid and enforceable.
- C. An order declaring that making, using, selling, offering to sell and/or importing the drug product of ANDA 91-465 will infringe, induce infringement of, and/or contributorily infringe the '214 patent.
- D. An injunction restraining and enjoining Defendants, their officers, agents, attorneys, and employees and those acting in privity or concert with all or any of them, from infringement, inducement of infringement, or contributory infringement of the '214 patent

through the commercial manufacture, use, sale, offer for sale or importation into the United States of the drug product of ANDA 91-465.

E. An order declaring the '867 patent valid and enforceable.

F. An order declaring that making, using, selling, offering to sell and/or importing the drug product of ANDA 91-465 will infringe, induce infringement of, and/or contributorily infringe the '867 patent.

G. An injunction restraining and enjoining Defendants, their officers, agents, attorneys, and employees and those acting in privity or concert with all or any of them, from infringement, inducement of infringement, or contributory infringement of the '867 patent through the commercial manufacture, use, sale, offer for sale or importation into the United States of the drug product of ANDA 91-465.

H. A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval to commercially make, use, sell, offer to sell or import the drug product of ANDA 91-465 be no earlier than the date following the expiration date of the '867 patent.

I. An order declaring this case exceptional and awarding attorneys' fees pursuant to 35 U.S.C. § 285.

J. Such other and further relief as the Court may deem just and proper.

Dated: December 4, 2009

CONNELL FOLEY LLP
Attorneys for Plaintiffs
Hospira, Inc. and Orion Corporation

By: /s Liza M. Walsh
Liza M. Walsh

85 Livingston Avenue
Roseland, New Jersey 07068
lwalsh@connellfoley.com
aantonian@connellfoley.com
Telephone: (973) 535-0500
Facsimile: (973) 535-9217

Of Counsel:
Thomas J. Meloro
Colman B. Ragan
Heather M. Schneider
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019
tmeloro@willkie.com
cragan@willkie.com
hschneider@willkie.com
Telephone: (212) 728-8000
Facsimile: (212) 728-8111

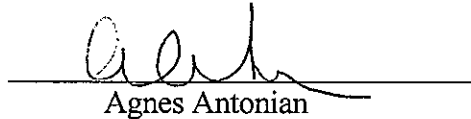
CERTIFICATION OF SERVICE

I, Agnes Antonian, caused a copy of Hospira, Inc. and Orion Corporation's Answer to Counterclaims to be served upon the following individuals via ECF and Email:

Eric I. Abraham, Esq.
Hill Wallack, LLP
202 Carnegie Center
CN 5226
Princeton, NJ 08543
Email: eia@hillwallack.com

David C. Doyle, Esq.
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
Email: ddoyle@mofo.com

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.


Agnes Antonian

DATED: December 4, 2009